



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/749,891 | 12/31/2003 | Timothy W. Foley | FOT-10002/44 | 8907 |
| 25006 7590 12/11/2007 GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C PO BOX 7021 TROY, MI 48007-7021 | | | EXAMINER JACKSON, BRANDON LEE | |
| | | | ART UNIT 3772 | PAPER NUMBER |
| | | | MAIL DATE 12/11/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/749,891 | Applicant(s) FOLEY, TIMOTHY W. | |
| | Examiner Brandon Jackson | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-11, 13-19 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Affidavit filed 5/22/2007 and amendments/arguments filed 10/15/2007. Currently, claims 1-6, 8-11, 13-19, and 21-24 are pending in the instant application.

Response to Arguments

The affidavit under 37 CFR 1.132 filed 5/22/2007 is insufficient to overcome the rejection of claims 1-77, 13-19, and 25-26 based upon Kallestad et al. (US Patent 3,943,924) in view of Jones et al. (US Patent 5,746,221) and Daskalon (US Patent 6,533,969) as set forth in the last Office action because: No evidence to support Applicant's assertion that the arrangement of the force transmitting layer in the outer wall and the material for the force transmitting layer consisting of a plurality of fibers is not obvious. Further the assertion that the success of the product in preventing or reducing injury should have relevancy as an indicia of the nonobviousness of the invention is not supported. No rebuttal evidence was supplied to sufficiently support Applicant's conclusion that the claimed invention prevents injury to the mouth or concussion. Applicant has provided no experimental data to show the number of mouth injuries to the users of the claimed invention have been reduced by the usage of the claimed invention. Moreover, Applicant cites the use of the device by the men's and women's basketball teams as examples of success. However, the use of mouthpiece's by basketball players is usually limited to less than half of the players on any given team because mouth injuries and concussions are rare basketball injuries. In addition, the

Examiner doubts the mouthpiece can prevent concussions, given concussions are usually caused by blows to the upper portion of the head, not the mouth region.

Applicant has given his opinion of the success of his own claimed invention and has not supported it with any experimental data or testimony from the users of the claimed invention. The claiming of usage by at least three sport's teams is not a sufficient showing of common success without testimony by the user's of the device to why the device is an improvement over other mouthpieces.

Applicant's arguments filed 10/15/2007 have been fully considered but they are not persuasive. Applicant argues the Jones reference does not teach the insert layer extending between the first molars or incisal and cervical portion of the tooth in the longitudinal direction. However, Jones teaches the insert extends the length of the mouthpiece, therefore, that would include between the first molars or incisal and cervical portion of the tooth in the longitudinal direction. Further, Applicant argues the Daskalon reference does not teach a force transmitting layer. However, the Daskalon reference is used in the rejection to provide a teaching of the fibers in a resin matrix used to make dental appliances. Applicant argues the force transmitting layer behind the teeth serves a completely different function from Applicant's force transmitting layer, which is in front of the teeth. However, they do serve the same function of absorbing the force after an impact with the dental region so the teeth do not have to absorb the force. Therefore, since they serve the same function it would require only ordinary skill in the art to move the force transmitting layer from the rear of the teeth to the front of the teeth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8-11, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kallestad et al. (US Patent 3,943,924) in view of Jones et al. (US Patent 5,746,221) and Daskalon et al. (US Patent 6,533,969). Kallestad discloses a mouthpiece (11) to protect the arch of a user (fig. 5) comprising a U-shaped channel (col. 2, lines 56-63), a force absorbing outer layer (7) with an outer wall, a force absorbing inner layer (5) with an inner wall, a lower wall (fig. 1) connecting the outer wall with the inner wall and covering the occlusal surface (fig. 5) of the teeth in the arch of the user and the inner wall only includes the force absorbing inner and outer layer (5, 7), and a force transmitting layer (9) disposed between the inner layer (5) and outer layer (7). The force transmitting layer (9) is generally planar preformed rectangular strip (fig. 1) and includes an arrangement of fibers of a resinous material (col. 3, lines 45-47)

for force to be distributed along, because a force transmitting layer inherently distributes force over the length of the structure. The force transmitting layer (9) extends from between the second premolar or bicuspid and the first molar on one side to between the second premolar or bicuspid and the first molar on the opposite side (fig. 5) of the teeth of a human user. The mouthpiece (11) covers the incisal to the cervical portion of human teeth (fig. 2). Also, the mouthpiece (11) comprises a palate protective wall (15) extending radially from the inner wall. The force absorbing inner and outer layers (5, 7) are made of dental materials having resilient, moldable, and settable properties (col. 3, lines 39-51). The force absorbing inner layer (5) inherently must have additives that allow it to be rigid at room temperature and moldable at a temperature greater than room temperature (col. 3, lines 39-44).

Kallestad fails to disclose a force transmitting layer transversely across the buccal surface of the teeth. However, Jones teaches a mouthguard comprising a force transmitting layer (17) transversely across the buccal surface of the teeth (fig. 5B). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the Kallestad device with the force transmitting layer across the buccal surface of the teeth, as taught by Jones, in order to absorb the energy and spread it across a wider area.

With respect to claims 6 and 16, Kallestad fails to disclose a gas-liberating chemical additive that liberates air bubbles. However, Applicant discloses that various types of chemical foaming agents are known in the art (p. 9, lines 14-16 of specification). Therefore, it would have been obvious to one having ordinary skill in the

art to have provided the mouthpiece of Kallestad with an inner layer having a chemical foaming agent, which Applicant admits is well known, to reduce the density of the mouthpiece.

Kallestad fails to disclose that the force transmitting layer includes a plurality of longitudinally extending fibers disposed in a resinous matrix or the material of the fibers and resin. However, Daskalon teaches a dental device comprising a fiber reinforced composite material (22) of dental grade with a polymeric matrix (col. 7, lines 62-64) including reinforcing fibers (col. 7, lines 62-64). The fibers are made from glass (col. 8, lines 21-25). The composite material may be a resin or polymeric material combined with a fiber material (col. 5, lines 10-13). The resin can be epoxy, acrylic, or polyester (col. 6, lines 37-48). The fibers longitudinally extending (col. 5, lines 52-59). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Kallestad device to be made of the materials, as taught by Daskalon, because of the high strength of the materials.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Application/Control Number:
10/749,891
Art Unit: 3772


Page 7


shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 12/3/07
Brandon Jackson
Examiner
Art Unit 3772


PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
12/2/07